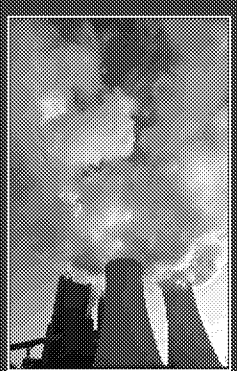
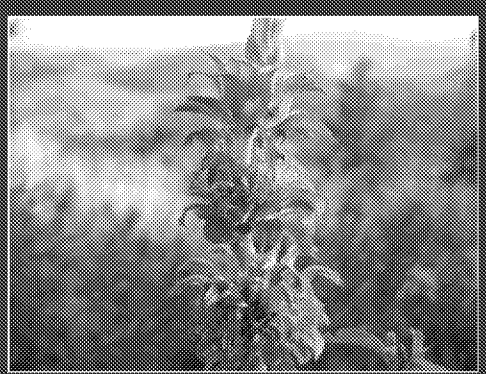
United States Environmental Protection Agency

Risk Assessment Basics (RAB) Course Series

Introduction: Risk Assessment and EPA's Office of Research and Development

Reading Packet

RAB 101


EPA's Risk Assessment Training and Experience (RATE) Program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RAB 101: Introduction to Risk Assessment and EPA's Office of Research and Development

READING PACKET

Risk Assessment Basics (RAB) Course Series

EPA's Risk Assessment Training and Experience Program

RAB 101: Introduction to Risk Assessment and EPA's Office of Research and Development

The objective of this course is to provide participants with a basic introduction to the fundamental concepts and terminology associated with risk assessments (e.g., human health, ecological, microbiological). How the risk assessment process is related to and informs risk management policies also will be covered. The mission and organizational structure of EPA's Office of Research and Development (ORD) also will be covered, focusing on how ORD performs research to identify and understand current and future environmental problems and how this research informs EPA's risk assessment goals. Finally, examples of how the Federal Government applies the risk assessment paradigm will be provided, including real-world examples of human health and ecological risk assessments.

For further reading:

NRC's "Red Book"

National Research Council (NRC). (1983) Risk Assessment in the Federal Government: Managing the Process. National Academies Press, Washington, DC.

EPA's Risk Assessment Portal

U.S. Environmental Protection Agency (U.S. EPA). (2010c) EPA's Risk Assessment Portal. Washington, DC. Available online at [HYPERLINK "http://www.epa.gov/riskassessment/index.htm"].

EPA's Office of Research and Development Home Page

U.S Environmental Protection Agency (U.S. EPA). (2010) EPA's Office of Research and Development.Washington, DC. Available online at [HYPERLINK "http://www.epa.gov/ord/"]

Table of Contents

[TOC \o "2-3" \h \z \u]

List of Figures

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List of Tables

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1. INTRODUCTION

1.1 What is Risk?

- The U.S. Environmental Protection Agency (EPA) defines risk as "the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor" [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Risk assessment processes are used to estimate risk in many fields, including finance and business, engineering, ecology, security, and human health.

1.2 History of Risk Assessment at EPA

The framework for EPA's risk assessment process began simultaneously with the creation of EPA in the 1970s when the Clean Water Act, Toxic Substances Control Act, and key amendments to the Clean Air Act were enacted by Congress. These and other pieces of environmental legislation provide regulatory protection for the environment and human health [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. Risk assessment is not specifically mentioned in this legislation because it did not emerge as a developed discipline at EPA until the late 1970s and early 1980s. The legislation did, however, call for action to investigate and regulate the potential for adverse effects on human and ecologic health caused by environmental agents and contaminants. Some key events are listed here.

- EPA was established in 1970.
- In 1975, EPA published its first risk assessment, "Quantitative Risk Assessment for Community Exposure to Vinyl Chloride."
- In 1980, the Society for Risk Analysis (SRA), an organization dedicated to the discussion and publication of risk assessment research was formed [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The first issue of SRA's journal, *Risk Analysis: An International Journal,* was published in 1981.
- In 1981, the National Research Council (NRC) organized the Committee on the Institutional Means for Assessment of Risks to Public Health to study risk assessment efforts and the possibility of unifying risk assessment processes within the government. Their report, *Risk Assessment in the Federal Government: Managing the Process*, more commonly referred to as the "Red Book," was released in 1983. The Red Book did not recommend changes to the organization of risk assessment in the government, but instead

provided an overall framework for completing risk assessments. This framework consisted of four steps and is still in use today. EPA has been drafting and publishing detailed guidelines for risk assessment, consistent with the Red Book, in the Federal Register since the mid-1980s [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The four steps are as follows:

- Hazard identification
- Dose-response assessment
- Exposure assessment
- Risk characterization.

- In the two-plus decades since the Red Book was published, the NRC has produced two follow-up reports. In 1994, *Science and Judgment in Risk Assessment* (referred to as the "Blue Book") was released. This report provided additional recommendations on how to improve aspects of the risk assessment process, including suggestions on how and why scientific judgment can and should be incorporated into the process [ADDIN LC_ITEM<references><reference><heroid>6424</heroid><citation>NRC (1994). Science and judgment in risk assessment. Washington, DC: National Research Council (NRC); National Academy Press .</citation><shortcitation>NRC</shortcitation><year>1994</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=6424</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. Recently, the NRC published a third volume, *Science and Decisions: Advancing Risk Assessment* (the "Silver Book"), which offers recommendations on how risk assessments and the concepts introduced in the previous reports should be used to accomplish effective risk-based decision-making [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Other contributions of the National Research Council include these publications:
  - *Improving Risk Communication* (1989)
  - *Understanding Risk* (1996)
  - *Toxicity Testing in the 21st Century* (2007)
  - *Phthalates and Cumulative Risk Assessment* (2008)
- The 1990 Clean Air Act Amendments called for the formation of the Presidential Commission on Risk Assessment and Risk Management (CRARM).
  - The purpose of the CRARM was to provide guidance on how to deal with residual emissions from hazardous air pollutants (HAPs) after technology-based controls have been placed on stationary sources of air pollutants.
  - But in examining this problem, the CRARM also developed a risk management framework that fosters an integrated approach to addressing complex, real-world issues that affect multiple environmental media and involve exposures to mixtures of chemicals.

Historically, most of EPA risk assessments have focused on single chemicals. More recently, however, scientific concern has grown over the potential health impacts of simultaneous exposure to multiple chemicals

(which can interact to alter risk) and the risk associated with the cumulative impact of all chemical exposures a person could experience through various exposure pathways (e.g., breathing air, drinking water, eating contaminated food, or contacting soil). The assessment of cumulative risk can also include psychological, social, physical, and other non-chemical stressors. The effects that multiple, simultaneous environmental exposures and cumulative exposures have on a person or ecosystems are unclear, however, making the calculation of specific risk difficult.

1.3 General Types of Risk Assessments at EPA

Typically, risk assessments involving all four components (hazard definition, dose-response assessment, exposure assessment, and risk characterization) are done on specific chemicals associated with an industrial site or other area. For example, if a chemical is released at a Superfund site, EPA might conduct a human health risk assessment for people at or near the site who could be exposed to this chemical.

Another type of risk assessment might be conducted on a community exposed to a specific environmental contaminant (e.g., from a local industrial plant). In this situation, EPA might conduct community-based risk assessments to evaluate whether people residing in the area have excess health risks compared to the general public.

Still other risk assessments are done on a widely dispersed pollutant, such as a contaminant in ambient air or one present in consumer products, to which the general population is exposed at some level.

1.4 Risk Assessment Paradigms

Figure 1. Risk Assessment Paradigm Based on NRC's 1983 Red Book

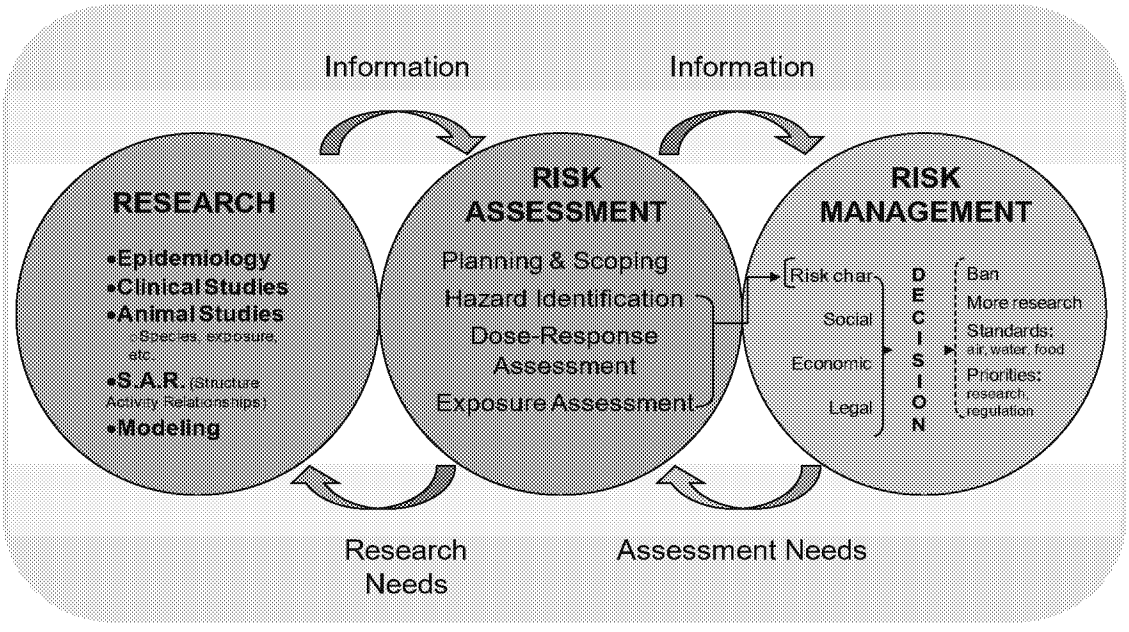
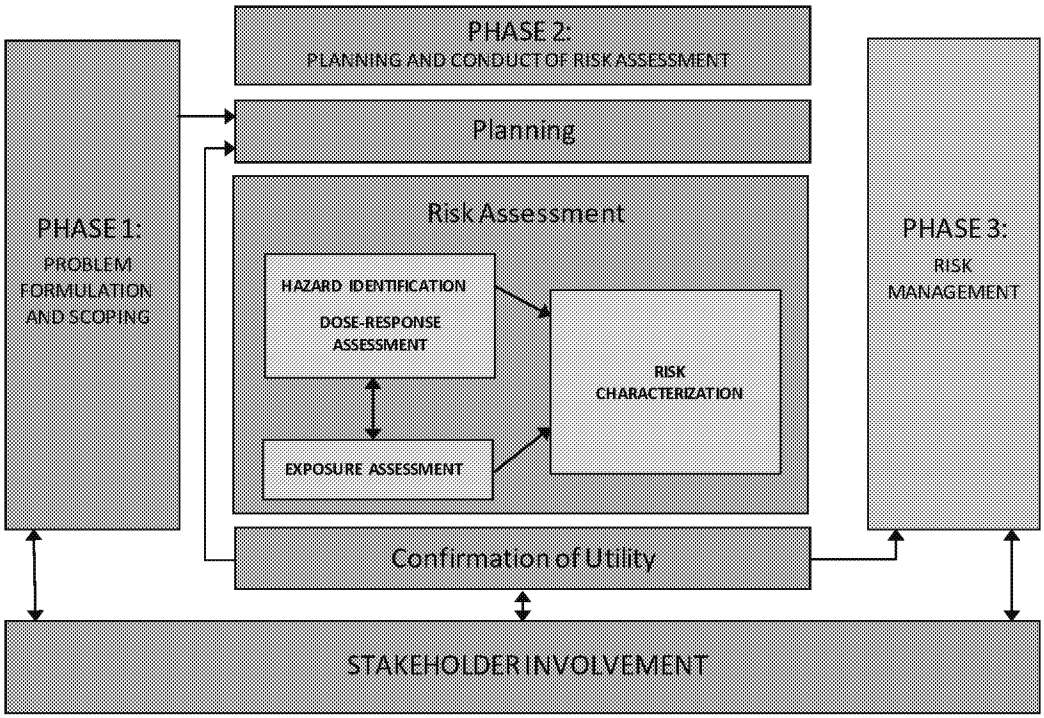


Figure 2. Updated Risk Assessment Paradigm Based on NRC's 2009 Silver Book



2. TERMINOLOGY

2.1 Primary Terminology

The following are general definitions for basic risk assessment terminology.

- **Risk assessment** is, in the context of human health, the evaluation of scientific information on the hazardous properties of environmental agents (hazard characterization), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment). The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree (risk characterization) [ADDIN LC_ITEM<references><reference><heroid>644574</heroid><citation>U.S. EPA (Environmental Protection Agency) (2003). Integrated Risk Information, Glossary of IRIS terms. National Center for Environmental Assessment (NCEA). Washington, D.C..http://www.epa.gov/iris/gloss8.htm.</citation><shortcitation>U.S.</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644574</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. More specifically, the four basic steps are described:
  - **Hazard identification** is the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (e.g., cancer, a birth defect) [ADDIN LC_ITEM<references><reference><heroid>644544</heroid><citation>NRC (National Research Council) (1983). Risk Assessment in the Federal Government: Managing the Process, . Washington, DC: National Academy Press.</citation><shortcitation>NRC</shortcitation><year>1983</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644544</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
  - **Hazard characterization** is "a description of the potential adverse health effects attributable to a specific environmental agent, the mechanisms by which agents exert their toxic effects, and the associated dose, route, duration, and timing of exposure" [ADDIN LC_ITEM<references><reference><heroid>644489</heroid><citation>U.S. EPA (2010). IRIS: Site help & tools. Retrieved August 23, 2010, from http://www.epa.gov/iris/help_ques.htm#process.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644489</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
  - **Dose-response assessment** (sometimes called **toxicity assessment**), as a part of hazard characterization, is the process of characterizing the relationship between dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent [ADDIN LC_ITEM<references><reference><heroid>644544</heroid><citation>NRC (National Research Council) (1983). Risk Assessment in the Federal Government: Managing the Process, . Washington, DC: National Academy Press.</citation><shortcitation>NRC</shortcitation><year>1983</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644544</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- Exposure assessment is an identification and evaluation of the human population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route, and duration of exposure [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Exposure is contact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, and gut).
- Risk characterization is the integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- Risk analysis is a phrase sometimes used synonymously with **risk assessment** but sometimes is used more broadly [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>] to include the ancillary processes of risk assessment such as risk management and risk communication.
- Risk communication involves the interactive exchange of information about risks among risk assessors, managers, news media, interested groups, and the general public (Duffus, 2001).
- Risk management is a decision-making process that accounts for political, social, economic, and engineering implications together with risk assessment information to develop, analyze, and compare management options and to select the appropriate managerial response to a potential chronic health hazard [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

2.2 Other Definitions for Risk Assessment

Several varying definitions for each concept, some more specific than others, are used when discussing risk assessment. The following list of definitions was adapted from EPA's Microbial Risk Assessment Thesaurus [ADDIN LC_ITEM<references><reference><heroid>635818</heroid><citation>U.S. EPA (2007). Thesaurus of terms used in microbial risk assessment. Retrieved May 11, 2010, from http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/microbial/T510.cfm.</citation><shortcitation>U.S. EPA</shortcitation><year>2007</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=635818</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>] and other sources. The Thesaurus includes general risk assessment terms that apply to microbial risk assessments as well as chemical and more general health and/or ecological risk assessments.

Risk Assessment is...

- The qualitative and quantitative evaluation of the risk posed to human health or the environment by the actual or potential presence or use of specific pollutants [ADDIN LC_ITEM<references><reference><heroid>635821</heroid><citation>U.S. EPA (1997). Terms of environment: Glossary, abbreviations and acronyms. U.S. Environmental Protection Agency. Washington, D.C.http://www.epa.gov/OCEPAterms/.</citation><shortcitation>U.S. EPA</shortcitation><year>1997</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=635821</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of establishing information regarding acceptable levels of a risk or levels of risk for an individual, group, society, or the environment [ADDIN LC_ITEM<references><reference><heroid>644554</heroid><citation>RAIS (Risk Assessment Information System) (2004). Glossary of Useful Terms Found in Risk Assessment. Retrieved , from http://rais.ornl.gov/homepage/glossary.shtml.</citation><shortcitation>RAIS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644554</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
- A scientifically based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization [ADDIN LC_ITEM<references><reference><heroid>644527</heroid><citation>CAC (Codex Alimentarius Commission) (1999). Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30. Retrieved , from http://www.who.int/foodsafety/publications/micro/cac1999/en/index.html.</citation><shortcitation>CAC</shortcitation><year>1999</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644527</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644528</heroid><citation>CAC (Codex Alimentarius Commission) (2003). Procedural Manual. Rome, Italy.http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y4971E/y4971e00.htm.</citation><shortcitation>CAC</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644528</link><format>Author</format><prefix></prefix><suffix>

></suffix></reference><reference><heroid>644535</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems, Annex 1 Glossary . http://www.who.int/foodsafety/publications/capacity/en/Englsih_Guidelines_Food_control.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644535</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644536</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Hazard Characterization for Pathogens in Food and Water, Guidelines. http://whqlibdoc.who.int/publications/2003/9241562374.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644536</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- A methodology for examining all possible risks involved with a particular product or organism. Risk assessment has four major parts: identification of hazards; dose response (how much exposure causes particular problems); exposure assessment (how much exposure is received during particular activities); and risk characterization (determining a probability that a risk will occur) [ADDIN LC_ITEM<references><reference><heroid>635821</heroid><citation>U.S. EPA (1997). Terms of environment: Glossary, abbreviations and acronyms. U.S. Environmental Protection Agency. Washington, D.C.http://www.epa.gov/OCEPAterms/.</citation><shortcitation>U.S. EPA</shortcitation><year>1997</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=635821</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
- A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (a related term is dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]

Hazard is...

- In a general sense, anything that has a potential to cause harm. In risk assessment, hazard (rather than "risk") can refer to the likelihood of experiencing a noncancer health effect [ADDIN LC_ITEM<references><reference><heroid>644580</heroid><citation>U.S. EPA (2004). Air toxics risk assessment reference library. Volume 1: Technical resource manual. Retrieved August 23, 2010, from http://www.epa.gov/ttn/fera/risk_atra_vol1.html.</citation><s

Hazard, **agent**, and **stressor** all can be used to indicate a potential source of harm. Although a hazard might not necessarily be a chemical agent, as it could be a psychological stressor rather than something physical, for the purposes of this course, they are synonymous. EPA denotes that "stressor" is the overarching term. EPA defines a stressor as "any physical, chemical, or biological entity that can induce an adverse response" (EPA, 2010a).

hortcitation>U.S. EPA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644580</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb [ADDIN LC_ITEM<references><reference><heroid>644554</heroid><citation>RAIS (Risk Assessment Information System) (2004). Glossary of Useful Terms Found in Risk Assessment. Retrieved , from http://rais.ornl.gov/homepage/glossary.shtml.</citation><shortcitation>RAIS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644554</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect [ADDIN LC_ITEM<references><reference><heroid>644528</heroid><citation>CAC (Codex Alimentarius Commission) (2003). Procedural Manual. Rome, Italy.http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y4971E/y4971e00.htm.</citation><shortcitation>CAC</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644528</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644535</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems, Annex 1 Glossary . http://www.who.int/foodsafety/publications/capacity/en/English_Guidelines_Food_control.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://

cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644535</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644536</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Hazard Characterization for Pathogens in Food and Water, Guidelines. http://whqlibdoc.who.int/publications/2003/9241562374.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644536</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- An inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
- A source of potential harm from past, current, or future exposures [ADDIN LC_ITEM<references><reference><heroid>644526</heroid><citation>ATSDR (Agency for Toxic Substances and Disease Registry) (2004). ATSDR Glossary of Terms. Retrieved August 23, 2010, from http://www.atsdr.cdc.gov/glossary.html.</citation><shortcitation>ATSDR</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644526</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

Dose is...

- The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism.
- The potential dose is the amount ingested, inhaled, or applied to the skin (μg/kg-day).

- The **applied dose** is the amount presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism) ($\mu g/m^3$).
- The **absorbed dose** is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of the skin, lung, and digestive tract) through uptake processes.
- **Internal dose** is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries (μg//kg).
- The amount of the chemical available for interaction by any particular organ or cell is termed the **delivered** or **biologically effective dose** for that organ or cell [ADDIN LC_ITEM<references><reference><heroid>644574</heroid><citation>U.S. EPA (Environmental Protection Agency) (2003). Integrated Risk Information, Glossary of IRIS terms. National Center for Environmental Assessment (NCEA). Washington, D.C..http://www.epa.gov/iris/gloss8.htm.</citation><shortcitation>U.S.</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644574</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>594981</heroid><citation>U.S. EPA (1997). Exposure factors handbook (final report). U.S. Environmental Protection Agency. Washington, DC. EPA/600/P-95/002F a-c. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464.</citation><shortcitation>U.S. EPA</shortcitation><year>1997</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=594981</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644580</heroid><citation>U.S. EPA (2004). Air toxics risk assessment reference library. Volume 1: Technical resource manual. Retrieved August 23, 2010, from http://www.epa.gov/ttn/fera/risk_atra_vol1.html.</citation><shortcitation>U.S. EPA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644580</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>626780</heroid><citation>U.S. EPA (2005). Guidelines for carcinogen risk assessment. Risk Assessment Forum, U.S. Environmental Protection Agency. Washington, DC. EPA/630/P-03/001B; PB2005-105899. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283.</citation><shortcitation>U.S. EPA</shortcitation><year>2005</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=626780</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The amount or concentration of undesired matter or energy deposited at the site of effect [ADDIN LC_ITEM<references><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The amount of a toxic component or the number of a pathogen that is ingested or interacts with an organism (host) [ADDIN LC_ITEM<references><reference><heroid>644479</heroid><citation>U. S. FDA (2002). Initiation and conduct of all 'major' risk assessments within a risk analysis framework: A report by the CFSAN risk analysis working group. Retrieved July 06, 2010, from http://webharvest.gov/peth04/20041031125526/http://www.cfsan.fda.gov/~dms/rafw-toc.html.</citation><shortcitation>U.</shortcitation><year>2002</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644479</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- The total amount of an agent administered to, taken up, or absorbed by an organism, system, or (sub)population [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The amount of agent that enters a target after crossing an exposure surface. If the exposure surface is an absorption barrier, the dose is an absorbed dose/uptake dose; otherwise, it is an intake dose [ADDIN LC_ITEM<references><reference><heroid>644537</heroid><citation>IPCS (International Programme on Chemical Safety) (2004). IPCS risk assessment terminology: Part 2. IPCS Glossary of Key Exposure Assessment Terminology. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/publications/methods/harmonization/en/compilation_nov2001.pdf.</citation><shortcitation>IPCS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644537</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

Dose-Response Assessment is...

- A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or as the probability of occurrence within a population [ADDIN LC_ITEM<references><reference><heroid>644580</heroid><citation>U.S. EPA (2004). Air toxics risk assessment reference library. Volume 1: Technical resource manual. Retrieved August 23, 2010, from http://www.epa.gov/ttn/fera/risk_atra_vol1.html.</citation><shortcitation>U.S. EPA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644580</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of characterizing the relationship between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent [ADDIN LC_ITEM<references><reference><heroid>644554</heroid><citation>RAIS (Risk Assessment Information System) (2004). Glossary of Useful Terms Found in Risk Assessment. Retrieved , from http://rais.ornl.gov/homepage/glossary.shtml.</citation><shortcitation>RAIS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644554</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological, or physical agent, and the severity or frequency of associated adverse health effects (response) [ADDIN LC_ITEM<references><reference><heroid>644527</heroid><citation>CAC (Codex Alimentarius Commission) (1999). Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30. Retrieved , from

http://www.who.int/foodsafety/publications/micro/cac1999/en/index.html.</citation><shortcitation>CAC</shortcitation><year>1999</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644527</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644528</heroid><citation>CAC (Codex Alimentarius Commission) (2003). Procedural Manual. Rome, Italy.http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y4971E/y4971e00.htm.</citation><shortcitation>CAC</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644528</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644536</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Hazard Characterization for Pathogens in Food and Water, Guidelines. http://whqlibdoc.who.int/publications/2003/9241562374.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644536</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]).

- An analysis of the relationship between the total amount of an agent administered to, taken up or absorbed by an organism, system or (sub)population and the changes developed in that organism, system or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose-response assessment is the second of four steps in risk assessment [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. It takes account of intensity of exposure, age pattern of exposure, and possibly other variables that might affect response. A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans. A dose-response assessment should describe and justify the methods of extrapolation used to predict incidence and should characterize the statistical and biologic uncertainties in these methods [ADDIN LC_ITEM<references><reference><heroid>644544</heroid><citation>NRC (National Research Council) (1983). Risk Assessment in the Federal Government: Managing the Process, . Washington, DC: National Academy Press.</citation><shortcitation>NRC</shortcitation><year>1983</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644544</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

Exposure is...

- Contact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, and gut) [ADDIN LC_ITEM<references><reference><heroid>644574</heroid><citation>U.S. EPA (Environmental Protection Agency) (2003). Integrated Risk Information, Glossary of IRIS terms.

National Center for Environmental Assessment (NCEA). Washington, D.C..http://www.epa.gov/iris/gloss8.htm.</citation><shortcitation>U.S.</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644574</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644580</heroid><citation>U.S. EPA (2004). Air toxics risk assessment reference library. Volume 1: Technical resource manual. Retrieved August 23, 2010, from http://www.epa.gov/ttn/fera/risk_atra_vol1.html.</citation><shortcitation>U.S. EPA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644580</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- The time integral of the concentration of a toxicant that is in the immediate vicinity of various ports of entry (such as lung, GI tract, and skin) [ADDIN LC_ITEM<references><reference><heroid>644554</heroid><citation>RAIS (Risk Assessment Information System) (2004). Glossary of Useful Terms Found in Risk Assessment. Retrieved , from http://rais.ornl.gov/homepage/glossary.shtml.</citation><shortcitation>RAIS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644554</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term (acute exposure), of intermediate duration, or long-term (chronic exposure) [ADDIN LC_ITEM<references><reference><heroid>644526</heroid><citation>ATSDR (Agency for Toxic Substances and Disease Registry) (2004). ATSDR Glossary of Terms. Retrieved August 23, 2010, from http://www.atsdr.cdc.gov/glossary.html.</citation><shortcitation>ATSDR</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644526</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Contact of a chemical, physical, or biological agent with the outer boundary of an organism, for example inhalation, ingestion, or contact with the skin [ADDIN LC_ITEM<references><reference><heroid>644532</heroid><citation>CRCWQT (Cooperative Research Centre for Water Quality and Treatment) (2002). Glossary of Water-Related Terms. Retrieved , from http://www.waterquality.crc.org.au/consumers/Consumersp17.htm.</citation><shortcitation>CRCWQT</shortcitation><year>2002</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644532</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- Concentration or amount of a particular agent that reaches a target organism, system or (sub)population in a specific frequency for a defined duration [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

Exposure Assessment is...

- An identification and evaluation of a population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route, and duration of exposure [ADDIN LC_ITEM<references><reference><heroid>644574</heroid><citation>U.S. EPA (Environmental Protection Agency) (2003). Integrated Risk Information, Glossary of IRIS terms. National Center for Environmental Assessment (NCEA). Washington, D.C..http://www.epa.gov/iris/gloss8.htm.</citation><shortcitation>U.S.</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644574</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644580</heroid><citation>U.S. EPA (2004). Air toxics risk assessment reference library. Volume 1: Technical resource manual. Retrieved August 23, 2010, from http://www.epa.gov/ttn/fera/risk_atra_vol1.html.</citation><shortcitation>U.S. EPA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=64580</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of identifying the pathways by which toxicants may reach individuals, estimating how much of a chemical an individual is likely to be exposed to, and estimating the number likely to be exposed [ADDIN LC_ITEM<references><reference><heroid>635821</heroid><citation>U.S. EPA (1997). Terms of environment: Glossary, abbreviations and acronyms. U.S. Environmental Protection Agency. Washington, D.C.http://www.epa.gov/OCEPAterms/.</citation><shortcitation>U.S. EPA</shortcitation><year>1997</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=635821</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment. [ADDIN LC_ITEM<references><reference><heroid>644554</heroid><citation>RAIS (Risk Assessment Information System) (2004). Glossary of Useful Terms Found in Risk Assessment. Retrieved , from http://rais.ornl.gov/homepage/glossary.shtml.</citation><shortcitation>RAIS</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644554</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644558</heroid><citation>SRA (2004). Glossary of Risk Analysis Terms . Retrieved August 23, 2010, from http://www.sra.org/resources_glossary.php.</citation><shortcitation>SRA</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644558</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The qualitative or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant [ADDIN LC_ITEM<references><reference><heroid>644527</heroid><citation>CAC (Codex Alimentarius Commission) (1999). Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30. Retrieved , from http://www.who.int/foodsafety/publications/micro/cac1999/en/index.html.</citation><shortcitation>CAC</shortcitation><year>1999</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644527</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644528</heroid><citation>CAC (Codex Alimentarius Commission) (2003). Procedural Manual. Rome,

Italy.http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y4971E/y4971e00.htm.</citation><shortcitation>CAC</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644528</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644536</heroid><citation>FAO/WHO (Food and Agriculture Organization/World Health Organization) (2003). Hazard Characterization for Pathogens in Food and Water, Guidelines. http://whqlibdoc.who.int/publications/2003/9241562374.pdf.</citation><shortcitation>FAO/WHO</shortcitation><year>2003</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644536</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

- Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure Assessment is the third step in the process of risk assessment [ADDIN LC_ITEM<references><reference><heroid>644555</heroid><citation>Safety) IIPoC (2004). IPCS/OECD Key Generic Terms Used in Chemical/Hazard Risk Assessment. Organisation for Economic Cooperation and Development (OECD).http://www.who.int/ipcs/methods/harmonization/areas/en/ipcsterminologyparts1and2.pdf.</citation><shortcitation>Safety)</shortcitation><year>2004</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644555</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].
- The process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposure that might arise from the release of new chemicals into the environment. In its most complete form, it describes the magnitude, duration, schedule, and route of exposures; the size, nature, and classes of the human populations exposed; and the uncertainties in all estimates. Exposure assessment identifies feasible prospective control options and predicts the effects of available control technologies on exposure [ADDIN LC_ITEM<references><reference><heroid>644544</heroid><citation>NRC (National Research Council) (1983). Risk Assessment in the Federal Government: Managing the Process, . Washington, DC: National Academy Press.</citation><shortcitation>NRC</shortcitation><year>1983</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644544</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

2.3 Terms with Different Meanings

Some terms have slightly different meanings depending on whether the risk assessment is conducted for human health or for ecosystems.

- Problem formulation is the phase in which the risk managers' charge to the assessors is converted into an actionable plan for performing the assessment [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>644559</heroid><citation>Suter G (2007). Ecological Risk Assessment. Boca Raton, FL: CRC Press.</citation><shortcitation>Suter</shortcitation><year>2007</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644559</link><format>Author</format><prefix></prefix><suffix></suffix></reference><reference><heroid>42805</heroid><citation>U.S. EPA (1998). Guidelines for ecological risk assessment. U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-95/002F. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460.</citation><shortcitation>U.S. EPA</shortcitation><year>1998</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=42805</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. Actionable plans vary depending on whether the risk assessment is for human health or ecosystems. A human health actionable plan might consider a particular health outcome, whereas an actionable plan for an ecological risk assessment might consider overall ecosystem health or the health of plants or animals as outcomes. The adjacent text box lists categories of methods that might be used during problem formulation in a risk assessment. Some of these are relevant only to human health (e.g., intake and internal dose models and health-outcome measurement). In general, the problem formulation for an

Selected Methods Considered in Problem Formulation

- Hazard-identification methods
- Stressor-characterization methods
- Source-characterization models and methods
- Environmental transport and fate models and methods
- Computational methods
- Uncertainty-characterization methods
- Intake and internal-dose models
- Dose-response models and methods
- Health-outcome measurement (risk measurement) methods
- Integrated cost-benefit methods
- Transparency, dissemination, and peer-review methods

Source: NRC [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>National Research Council (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council. Retrieved from: http://www.nap.edu/catalog/12209.html.</citation><shortcitation>National Research Council</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Year</format><prefix></prefix><suffix></suffix></reference></references>]

ecological risk assessment is defined more broadly than for human health risk assessments.

- An **analysis plan** is a specific product of problem formulation, which serves as a work plan that "outlines the analytic and interpretive approaches that will be used in the risk assessment" [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. As with actionable plans, the specific analysis plan for risk assessments varies depending on the discipline.
- The term **risk profile** in ecological risk assessment refers to steps analogous to the dose-response and exposure steps in human health risk assessments.
- **Planning and scoping** is a deliberative process that helps decision-makers defining a risk-related problem [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. It primarily involves a discussion between decision-makers (risk managers) and stakeholders (people who have vested interests in the outcome of the assessment) in which assessors have a supporting role. Further, planning and scoping determines which risk-mitigation options (to reduce risk) are of concern for the assessment and sets boundaries for the assessment (that is, its purpose, structure, content, and so on)" [ADDIN LC_ITEM<references><reference><heroid>180073</heroid><citation>NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Research Council.</citation><shortcitation>NRC</shortcitation><year>2009</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=180073</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The decision-makers and stakeholders inherently differ for each discipline conducting a risk assessment, and the particular risk determines the specific planning.

3. RISK ASSESSMENT AND RISK MANAGEMENT AT ORD

The research conducted by the Office of Research and Development (ORD) forms the foundation of the Agency's science and technology programs. By fostering innovative ways to prevent pollution and reduce risk to human and ecological health, ORD helps improve the quality of air, water, and soil to benefit both people and ecosystems. Resource management and environmental forecasting are also key areas of focus at ORD, helping prepare the Agency to anticipate and effectively address potential issues.

ORD's mission is to:

- Perform research and development to identify, understand, and resolve current and future environmental problems
- Provide responsive technical support to EPA
- Integrate the work of ORD's scientific partners (other agencies, nations, private-sector organizations, and academia)
- Provide leadership in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.

As part of ORD, EPA's National Center for Environmental Assessment (NCEA) serves as the national resource center for human health and ecological risk assessment. NCEA provides guidance and conducts risk assessments to protect human health and the environment for criteria pollutants and hazardous air pollutants (HAPs). Thus, NCEA occupies a critical position between scientists in ORD and management in EPA's program and regional offices supporting regulatory, enforcement, and remedial-action decisions [ADDIN LC_ITEM<references><reference><heroid>644491</heroid><citation>U.S. EPA (2010). Office of research and development: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/ord/htm/aboutord.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644491</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

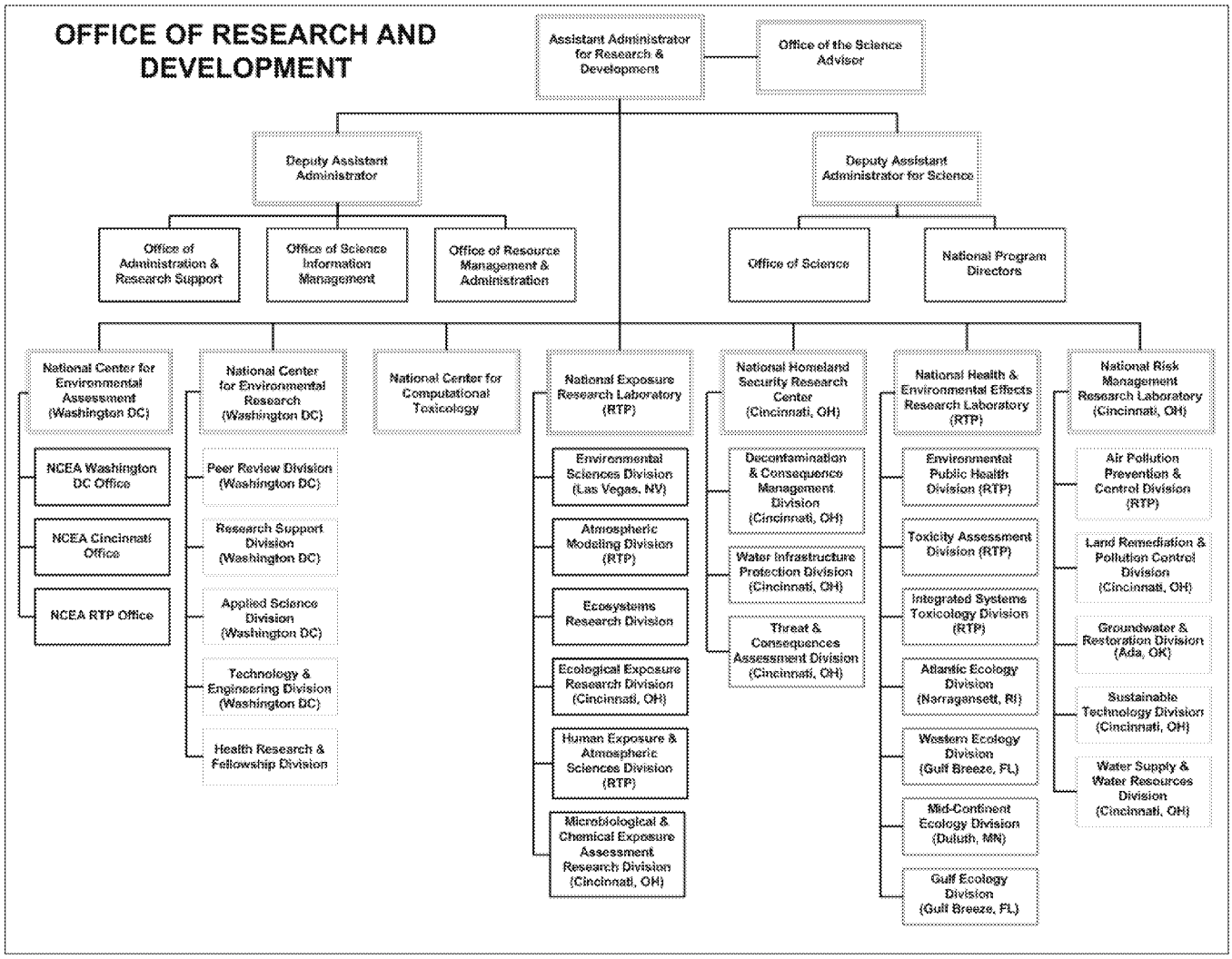
NCEA fulfills its mission by:

- Developing guidelines, methodologies, and training such as:
  - Guidelines for Carcinogen Risk Assessment [ADDIN LC_ITEM<references><reference><heroid>626780</heroid><citation>U.S. EPA (2005). Guidelines for carcinogen risk assessment. Risk Assessment Forum, U.S. Environmental Protection Agency. Washington, DC. EPA/630/P-03/001B; PB2005-105899. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283.</citation><shortcitation>U.S. EPA</shortcitation><year>2005</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=626780</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
  - Guidelines for Ecological Risk Assessment [ADDIN LC_ITEM<references><reference><heroid>42805</heroid><citation>U.S. EPA (1998). Guidelines for ecological risk assessment. U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-95/002F. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460.</citation><shortcitation>U.S. EPA</shortcitation><year>1998</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=42805</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]

  - Exposure Factors Handbook [ADDIN LC_ITEM<references><reference><heroid>594981</heroid><citation>U.S. EPA (1997). Exposure factors handbook (final report). U.S. Environmental Protection Agency. Washington, DC. EPA/600/P-95/002F a-c. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464.</citation><shortcitation>U.S. EPA</shortcitation><year>1997</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=594981</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
  - Child-Specific Exposure Factors Handbook [ADDIN LC_ITEM<references><reference><heroid>196062</heroid><citation>U.S. EPA (2008). Child-specific exposure factors handbook. U.S. Environmental Protection Agency. Washington, D.C.. EPA/600/R-06/096F. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243.</citation><shortcitation>U.S. EPA</shortcitation><year>2008</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=196062</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]
- Creating and maintaining tools and data bases
  - Integrated Risk Information System (IRIS)
  - Benchmark Dose Software (BMDS)
- Integrating and applying ORD- and extramural-generated research
- Performing risk assessments
- Consulting with EPA programs, regions, and decision-makers

The organizational chart for ORD is shown in Figure 3.

Figure 3. Organization of EPA's Office of Research and Development



3.1 How Risk Assessment Informs Risk Management at EPA

The concepts and goals of risk assessment and risk management are distinguishable, but opinions vary on the degree of separation between risk assessment and risk management in practice. Risk management decisions were formerly embedded within risk assessments and not necessarily clearly identified as management decisions. More recently, efforts have been made to separate risk assessment from risk management with an emphasis placed on the iterative process between risk managers and risk assessors along with documented transparency.

At EPA, risk assessments inform Agency actions such as rules, regulations, standards, and guidance (e.g., Clean Water Act, ambient water quality criteria). If planning and scoping and problem formulation are done properly, then risk assessment can inform the decision making process in a way that is helpful to risk managers.

Decision making is a risk management activity. EPA considers risk management as the process that evaluates how to protect public health. Examples of risk management actions include deciding how much of a substance a company is allowed to discharge into a river (Office of Water); determining allowable levels of contamination

in drinking water (Office of Water); establishing national ambient air quality standards (Office of Air Quality Planning and Standards); deciding which substances can be stored at a hazardous waste disposal facility (Office of Solid Waste and Emergency Response); and deciding to what extent a hazardous waste site on EPA's National Priorities List (i.e., the "Superfund" list) must be cleaned up (Office of Solid Waste and Emergency Response).

Risk assessment is an underlying component of one of at least seven factors that can form the basis of risk management decisions [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>] (see Figure 4):

- Scientific factors provide the basis for the **risk assessment**, including information drawn from toxicology, chemistry, epidemiology, ecology, mathematics, and other disciplines.
- Economic factors inform the manager on the cost of risks and the benefits of reducing them, the costs of risk mitigation or remediation options, and the distributional effects.
- Laws and legal decisions define the basis for the Agency's risk assessments, management decisions, and, in some instances, the schedule, level, or methods for risk reduction.
- Social factors, such as income level, ethnic background, community values, land use, zoning, availability of health care, lifestyle, and psychological condition of the affected populations, can affect the susceptibility of an individual or a definable group to risks from a particular stressor.
- Technological factors include the feasibility, impacts, and range of risk management options.
- Political factors are based on the interactions among branches of the Federal Government, with other federal, state, and local government entities, and even with foreign governments. Such factors can range from practices defined by Agency policy and political administrations through inquiries from members of Congress, special interest groups, or concerned citizens.
- Public values reflect the broad attitudes of society about environmental risks and risk management.

3.2 How Environmental Research Informs EPA's Risk Assessment Goals

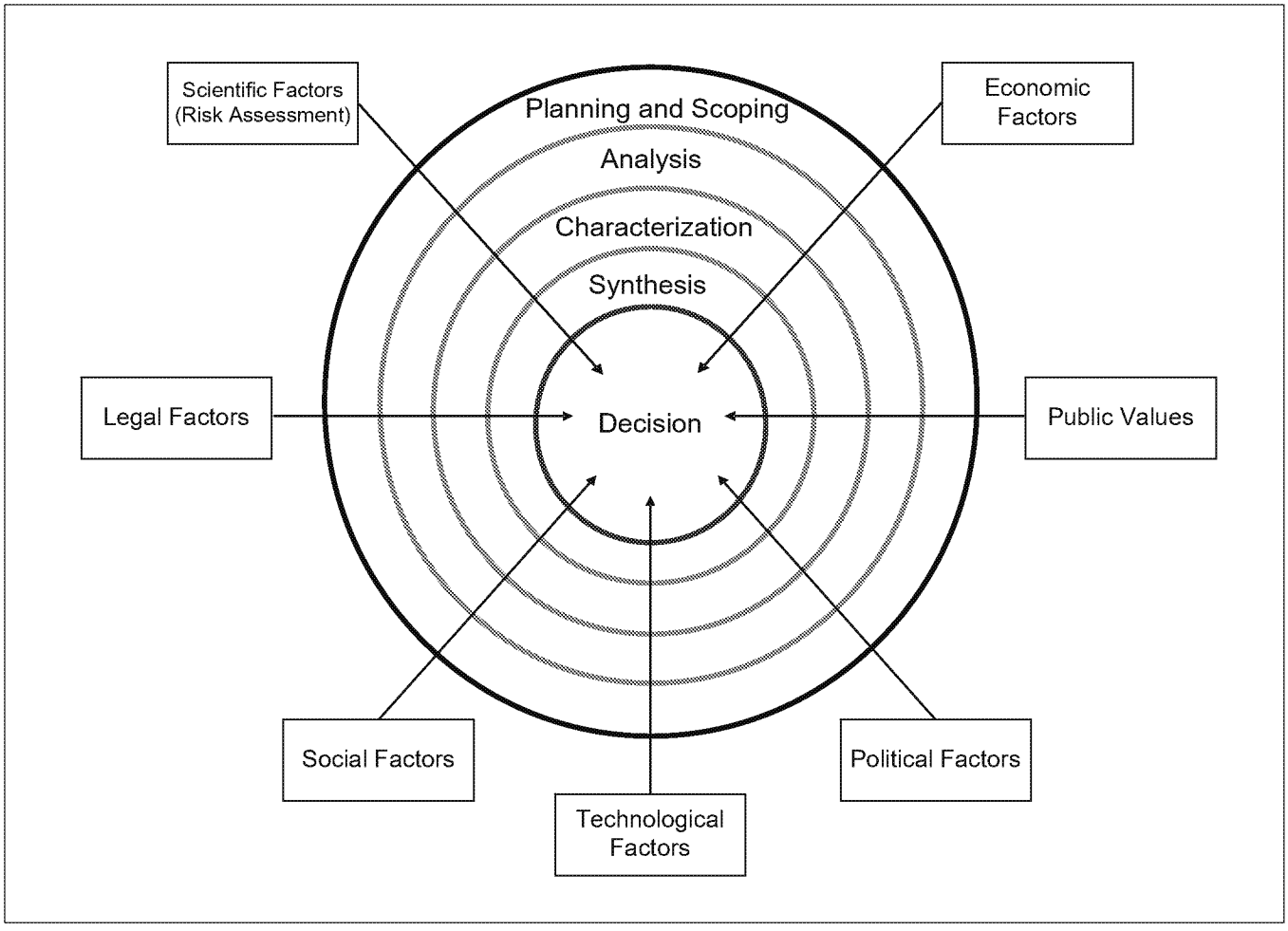
Research at EPA is important for identifying environmental and health hazards and carrying out human health risk assessments to estimate potential harm. Many research programs at EPA are aimed specifically at improving methods and information for use in risk assessment.

- EPA develops guidelines and handbooks for risk assessment using the latest research and knowledge on risk assessment methods. EPA-wide guidance documents for risk assessment can be found at [HYPERLINK "http://epa.gov/riskassessment/guidance.htm"].
- EPA databases (such as HEDS, the Human Exposure Database System) and tools (such as exposure modeling programs) are often used in risk assessments within and outside of the EPA. See [HYPERLINK "http://www.epa.gov/riskassessment/guidance.htm" \l "dbs"] for more EPA research programs.
- IRIS (the Integrated Risk Information System) is a searchable EPA database that "evaluates risk information on effects that may result from exposure to environmental contaminants" [ADDIN LC_ITEM<references><reference><heroid>644489</heroid><citation>U.S. EPA (2010). IRIS: Site help

& tools. Retrieved August 23, 2010, from http://www.epa.gov/iris/help_ques.htm#process.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644489</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. IRIS contains information on more than 540 chemicals. The IRIS database is located at [HYPERLINK "http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList"].

- IRIS health assessments comprise the hazard identification and dose-response assessment steps [of a risk assessment]. Information in IRIS assessments, combined with site- or problem-specific exposure assessments, forms the scientific basis for EPA's risk management decisions.

Figure 4. Risk Management Decision Framework (U.S. EPA, 2000a)



Source: [ADDIN LC_ITEM<references><reference><heroid>644493</heroid><citation>U.S. EPA (2010). Risk assessment: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/riskassessment/basicinformation.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644493</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]

- IRIS assessments provide quantitative health reference values such as the reference dose (RfD) and reference concentration (RfC).
  - The RfD is an estimate (with uncertainty that can span an order of magnitude) of daily oral exposure to the human population (including sensitive subgroups) that is unlikely to cause appreciable risk of

deleterious effects during a lifetime [ADDIN LC_ITEM<references><reference><heroid>644487</heroid><citation>U.S. EPA (2010). Diesel exhaust. Retrieved August 23, 2010, from http://www.epa.gov/IRIS/subst/0642.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644487</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The units for RfD are in milligrams of substance per kilogram of bodyweight per day.

- The RfC is conceptually similar to the RfD, but it is developed considering continuous inhalation exposure rather than a daily oral exposure. The units for RfC are in milligrams of substance per cubic meter of air breathed. Primary research in toxicology, exposure, and related fields conducted at EPA labs (such as ORD's National Health and Environmental Effects Research Laboratory) can be used to support the development of reference doses and concentrations.

4. EXAMPLES OF RISK ASSESSMENT IN PRACTICE AT EPA

4.1 Development of Fish Consumption Advisories Using an IRIS RfD

Some chemical pollutants can bioaccumulate in fatty tissues or bind to muscle tissue of fish and shellfish. Even very low concentrations of these pollutants in the water or sediment can result in fish or shellfish tissue concentrations high enough to pose health risks to consumers. Methylmercury (MeHg), a common contaminant in fish, accumulates in the muscle tissue of the fillet and cannot be removed by trimming or properly cooking the fish. EPA and state agencies use IRIS values to set human consumption limits for fish based on fish tissue concentration of contaminants.

Presented below is a recommended consumption limit table developed for methylmercury in fish, based on an IRIS RfD for MeHg of 1 x 10^{-4} mg/kg-day [ADDIN LC_ITEM<references><reference><heroid>644583</heroid><citation>U.S. EPA (2002). Methylmercury (MeHg) (CASRN 22967-92-6). U.S. Environmental Protection Agency. Washington, DC.http://www.epa.gov/ncea/iris/subst/0073.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2002</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644583</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. Variables used to calculate the consumption limits include fish meal size, consumer body weight, contaminant concentration in the fish tissue, the time-averaging period selected (monthly), and the RfD for noncancer health endpoints. This table indicates, for example, that if samples of a certain type of fish from a known body of water/source have a concentration greater than 1.9 parts per million, EPA would recommend that no fish be eaten [ADDIN LC_ITEM<references><reference><heroid>644595</heroid><citation>U.S. EPA (2000). National guidance: Guidance for assessing chemical contaminant data for use in fish advisories. Volume 2. Risk assessment and fish consumption limits . U.S. Environmental Protection Agency. Washington, DC. EPA 823-B-00-008. http://www.epa.gov/waterscience/fish/advice/volume2/index.html.</citation><shortcitation>U.S.</shortcitation><year>2000</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644595</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>].

To read more about fish advisories, visit [HYPERLINK "http://www.epa.gov/waterscience/fish/index.html"]. Guidance for assessing chemical contaminant data for use in fish advisories can be found at [HYPERLINK "http://www.epa.gov/waterscience/fish/technical/guidance.html"].

Table [SEQ Table * ARABIC]. Monthly Fish Consumption Limits for Noncarcinogenic Health Endpoint – Methylmercury

Noncancer Health Endpoints[a]	Risk Based Consumption Limit[b]
Fish Tissue Concentrations (ppm, wet weight)	Fish Meals/Month
0 – 0.029	Unrestricted (>16)
>0.029 - 0.059	16
>0.059 - 0.078	12
>0.078 - 0.12	8
>0.12 – 0.23	4
>0.23 – 0.31	3

>0.31 – 0.47	2
>0.47 – 0.94	1
>0.94 – 1.9	0.5
>1.9	None (<0.5)

[a] Chronic, systemic effects.
[b] The assumed meal size is 8 oz. (0.227 kg). The ranges of chemical concentrations presented are conservative, e.g., the 12-meal-per-month levels represent the concentrations associated with 12–15.9 meals.

Notes:
1. Consumption limits are based on an adult body weight of 70 kg and an RfD of 1 x 10^{-4} mg/kg-d.
2. None = No consumption recommended.
3. Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD). When the monthly limit is consumed in less than 1 month, the daily dose could exceed the RfD.

4.2 Development of the Integrated Science Assessment for Carbon Monoxide

Integrated Science Assessments (ISAs) support the periodic review of science upon which the NAAQS are based. ISAs accurately reflect "the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health which may be expected from the presence of [a] pollutant in ambient air" (42 U.S.C. 7408 in [ADDIN LC_ITEM<references><reference><heroid>626035</heroid><citation>U.S. EPA (2010). Integrated science assessment for carbon monoxide (final report). U.S. Environmental Protection Agency. Washington, DC. EPA/600/R-09/019F. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=218686.</citation><shortcitation>U.S.</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=626035</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The NAAQS are actually two parts, with the primary designed to protect human health and the secondary associated with the protection of human welfare and ecological systems. When no secondary standard is specified, the secondary standard is typically the same as the primary standard.

- The ISA for carbon monoxide focuses on recent information addressed by specific questions in the integrated plan used to review the NAAQS. Under the Clean Air Act, EPA must periodically review and revise the NAAQS to reflect current scientific information.
  - An example of a question posed is: "To what extent is key scientific evidence becoming available to improve our understanding of the health effects associated with various time periods of CO exposures including not only daily but also chronic (months to years) exposures?"

As a part of the ISA, detailed literature searches for studies relating to carbon monoxide were conducted, with studies evaluated for their quality. This information was used to determine which studies contained useful or new data on health effects from carbon monoxide exposure that could inform decisions on whether to retain or revise the existing standard.

- A major conclusion was that the new research summarized in the carbon monoxide ISA reduced many uncertainties noted in the 2000 Carbon Monoxide Air Quality Criteria Document [ADDIN LC_ITEM<references><reference><heroid>644491</heroid><citation>U.S. EPA (2010). Office of research and development: Basic information. Retrieved August 23, 2010, from http://www.epa.gov/ord/htm/aboutord.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644491</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. EPA concluded the research demonstrated that non-ambient exposure did not influence effects estimates in

epidemiologic studies, that epidemiologic study results are consistent and robust in co-pollutant models, and that ischemia-related outcomes are coherent with evidence from controlled human exposure studies. EPA also concluded that the evidence from epidemiologic and human clinical studies, supported by the biological plausibility provided by the role of carbon monoxide in limiting oxygen availability, is sufficient to conclude that relevant short-term carbon monoxide exposures are likely related to cardiovascular morbidity.

The Office of Air Quality Planning Standards (QAQPS) in the Office of Air and Radiation (OAR) uses the information presented in ISAs to develop quantitative and qualitative estimates of the exposures and risks of adverse health and welfare effects associated with possible levels of the criteria pollutants.

The full CO ISA is available at [HYPERLINK "http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=218686"]. Information on the CO Standard that the Clean Air Act requires EPA to establish can be found at [HYPERLINK "http://www.epa.gov/ttnnaaqs/standards/co/s_co_index.html"]. For more information on carbon monoxide in general, see [HYPERLINK "http://www.epa.gov/iaq/co.html"].

4.3 Preparation of the IRIS Assessment of Diesel Exhaust

Diesel engine exhaust is a complex mixture of airborne particles and gases. Diesel particulate matter, which includes elemental carbon particles and adsorbed organic compounds, is the most frequently determined measure of diesel exhaust. Diesel particulate matter is the measure reported in toxicological studies of diesel engine exhaust [ADDIN LC_ITEM<references><reference><heroid>644487</heroid><citation>U.S. EPA (2010). Diesel exhaust. Retrieved August 23, 2010, from http://www.epa.gov/IRIS/subst/0642.htm.</citation><shortcitation>U.S. EPA</shortcitation><year>2010</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644487</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. EPA has prepared an IRIS assessment of diesel engine exhaust; some of the key results of this assessment are presented here.

- The IRIS profile for diesel engine exhaust contains risk values for inhalation (including an RfC) of diesel exhaust and a summary of its potential to cause cancer. The profile is based on the premise that thresholds exist for noncancer effects, such as pulmonary inflammation and cellular necrosis, or that a certain amount of chemical to which a person can be exposed each day throughout his or her lifetime would not be expected to cause toxic effects. Above this "threshold," however, a person might experience deleterious health effects.
- The RfC for diesel engine exhaust was derived by using state-of-the-science dosimetry models for lung effects. This illustrates how scientific information can influence risk assessment.
- The studies used to derive the RfC showed similar health effects (mainly chronic inflammation of and structural changes to the lung) that were more severe as the level of diesel engine exhaust increased.
- Data were not available (as of 2003) to quantitatively estimate the risk of cancer for diesel engine exhaust; the IRIS document, however, summarizes the potential for carcinogenicity in humans in "Weight of Evidence" or WOE.

Government and private entities can use this IRIS risk information in combination with exposure data specific to the population with which they are concerned to fully characterize human health risks. EPA has also used this information on diesel engine exhaust to conclude that the current National Ambient Air Quality Standard (NAAQS) relating to diesel particulate matter is protective based on the current data.

For the full IRIS profile of diesel engine exhaust, see: [HYPERLINK "http://www.epa.gov/IRIS/subst/0642.htm"].

4.4 Use of IRIS Values to Evaluate Health Risks: Casmalia Resources Superfund Site, Casmalia, California

The Casmalia Resources Superfund Site (CRSS) is an inactive hazardous waste management facility located in the northwestern corner of Santa Barbara County, California [ADDIN LC_ITEM<references><reference><heroid>644531</heroid><citation>CDHS (California Department of Health Services) (2008). Public Health Assessment for Casmalia Resources Superfund Site, Casmalia, Santa Barbara County, California. EPA FACILITY ID:CAD020748125. Prepared for the U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.http://www.atsdr.cdc.gov/hac/PHA/CasmaliaResources/CasmaliaResources092805PHA.pdf..</citation><shortcitation>CDHS</shortcitation><year>2008</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644531</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]. The site no longer accepts waste and no exposed waste occurs at the site. Community members were concerned that they continued to be exposed to contaminants from the site, so EPA conducted a public health assessment for the site. As a part of this assessment, EPA investigated previously identified contaminants and their past and current levels in the air and water of the community. Using available IRIS values as references, they evaluated the potential for health problems from these exposures. Levels of hydrogen sulfide and acrolein at the site were elevated; measured concentrations of these substances were compared to IRIS RfCs to evaluate the potential for harm. The report concluded the following [ADDIN LC_ITEM<references><reference><heroid>644531</heroid><citation>CDHS (California Department of Health Services) (2008). Public Health Assessment for Casmalia Resources Superfund Site, Casmalia, Santa Barbara County, California. EPA FACILITY ID:CAD020748125. Prepared for the U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.http://www.atsdr.cdc.gov/hac/PHA/CasmaliaResources/CasmaliaResources092805PHA.pdf..</citation><shortcitation>CDHS</shortcitation><year>2008</year><link>http://cfpub.epa.gov/ncea/hero/index.cfm?action=search.view&reference_id=644531</link><format>Author</format><prefix></prefix><suffix></suffix></reference></references>]:

- Maximum hydrogen sulfide concentrations were estimated to be present in the town of Casmalia at a level nearly 1,000 times the EPA's RfC listed in IRIS of 1.43 parts per billion in air. At this level, exposures can result in burning or irritation of the throat and lungs, and these effects were documented by physicians in individuals near the site. Individuals such as ranchers who work near the site might have been exposed to higher levels than those estimated to be present in the town of Casmalia.
- The average hazard quotient for estimated chronic exposures to hydrogen sulfide was calculated to be 22. A hazard quotient is the relative proportion of an exposure compared to the health comparison value (in this case, the RfC) for a single chemical. An acceptable hazard quotient is typically less than 1; if it exceeds 1, the possibility exists for noncancer health effects.
- Maximum detected concentrations of acrolein were estimated to be present in the town of Casmalia at levels 15 times the health comparison value (EPA's RfC from IRIS) of 0.009 parts per billion. The average detection was more than 7 times the health comparison level. The RfC was based on animal studies that identified histopathological changes in the nasal cavity, lung, larynx, and trachea in rats. Based on the uncertainties regarding health effects of exposure to humans, however, in addition to the uncertainty

regarding the duration of the exposures to acrolein, it was not possible to determine whether any health effects could be attributed to this exposure. The average hazard quotient for acrolein was 4.15.

The full report of the CRSS is available at [HYPERLINK "http://www.atsdr.cdc.gov/hac/PHA/CasmaliaResources/CasmaliaResources092805PHA.pdf"].

Based on these comparisons and other analyses, remedial actions were selected for the site, including:

- Capping the landfills designated for pesticides and solvents, heavy metals, caustics and cyanide, acids, and PCBs;
- Installing and operating a ground water collection and treatment system;
- Consolidating and managing waste water collection and containment impoundments; and
- Implementing site improvements such as slope stabilization and minimizing the amounts of infiltrating rainwater.

The remedial actions selected were intended to ensure that the hazardous wastes disposed of at the site are stable and contained for a long time and that the hazardous wastes do not enter the ground water, air, or soil near the site.

REFERENCES

[ADDIN LC_BIBL]

Additional Reference (to be added to HERO):

Duffus, J. 2001. Risk Assessment Terminology. *Chemistry International* 23(2). International Union of Pure and Applied Chemistry.